Strategies to Promote Consistency in the Implementation of the Produce Safety Rule

OUTLINE

1. Introductions and Housekeeping

2. Roles of Responsibilities

- Instructors
  - Assist participants in correctly and consistently implementing the PSR
  - Not to promote one State plan better than another
  - Not to negatively review the PSR

- FDA for this meeting (if FDA is represented)
  - Subject Matter Experts in understanding the rule so that it can be appropriately applied
  - Not to discuss how the agency would write an observation

- Other Guests (if any)

3. Review the Meeting Will NOT Cover

- How to conduct an inspection

- How to write an observation

4. Understanding to Apply

21 CFR 112 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

- Learning the language of the PSR

- Knowing the PSR

- Understanding the PSR

- Applying the PSR (discuss the use of scenarios and/or farm visit)

5. Resources

The Produce Safety Rule

Understanding the underlying science and rationale for key provisions

➢ ***HANDOUT 1- Produce Safety Rule with Preamble***

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FDA Resources for Growers

- Guidance documents: *Note: The inspections are not based on the guidance but the PSR
  - ***HANDOUT 2*** ***Draft Guidance for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry***

- At a Glance documents: **Note: Can also use at a glance documents in discussing specific subparts*
  - ***HANDOUT 3*** ***At a Glance: Chapter 1: General Provisions (Subpart A)***
  - ***HANDOUT 4*** ***At a Glance Chapter 2: Personnel Qualifications and Training (Subpart C)***
  - ***HANDOUT 5*** ***At a Glance Chapter 3: Health and Hygiene (Subpart D)***
  - ***HANDOUT 6*** ***At a Glance Chapter 4: Biological Soil Amendments of Animal Origin and Human Waste (Subpart F)***
  - ***HANDOUT 7*** ***At a Glance Chapter 5: Domesticated and Wild Animals (Subpart I)***
  - ***HANDOUT 8*** ***At a Glance Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K)***
  - ***HANDOUT 9*** ***At a Glance Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L)***
  - ***HANDOUT 10*** ***At a Glance Chapter 8: Records (Subpart O)***

6. Review of the Subparts: Subpart A: Coverage, Non-Coverage and Qualified Exemption Criteria

- Subpart A (Definitions)
  - ***HANDOUT 11*** ***FDA Glossary of Key Terms***

- What is a farm?
  - Based on activities (examples of grazing and wild harvest; pick your own) and produce

- What is a covered farm?
  - ***HANDOUT 12*** ***FDA Fact Sheet: Coverage and Exemptions***

- Produce Sales and Food Sales, where do the numbers come from?
  - 25K, 250K, 500K
    - **HANDOUT 13** **FSMA Inflation Adjusted Cut Offs**
- Covered Activities
  - What are covered activities?
    - ***HANDOUT 14*** ***At a Glance: Chapter 1: General Provisions (Subpart A)***
    - Discuss covered activities in your state/region
      - ***HANDOUT 15*** ***Covered Activity Definition and Examples***
  - What are NOT covered activities?
    - ***HANDOUT 16*** ***Not Covered Activities***
  - Examples of activities that might be covered or not covered
    - **HANDOUT 17** ***Examples of Not Covered Activities***

- Qualified exemption
  - ***HANDOUT 18 Qualified Exemption***
  - ***HANDOUT 19 Qualified Exemption What Does That Mean?***
  - re the terms "Not Covered" and "Qualified Exemption" interchangeable?
  - What does it mean to be "eligible" for a qualified exemption?

- What happens if the grower does not want to be not covered or claim an exemption (commercial or monetary)?

- Growers obligations
  - Does Exemption mean "No rules apply to me?"
  - Resources for determining Qualified Exemption
    - ***HANDOUT 20 PSA Qualified Exemption Review Template – page 5***
      - ***If your state has a Qualified Exemption Calculation Template, review at this time instead.***

7. Review of Rule: Subparts C through O

Scenarios used in this section should be developed by each state/region to be reflective of actual on farm activities in the state/region. These two handouts are examples only.

- ***HANDOUT 21 Jim's Watermelon Farm Scenario (examples of scenarios)***
- ***HANDOUT 22 Talladega Cilantro Farm Scenario (examples of scenarios)***

- Subpart C
  - ***HANDOUT 23 FDA Fact Sheet Required Training for Covered Farms***
  - Use scenarios developed for actual on farm activities in the state/region.

- Subpart D
  - Use scenarios developed for actual on farm activities in the state/region.

- Subpart *F
  - ***HANDOUT 24 FDA Fact Sheet Biological Soil Amendments of Animal Origin***
  - ***HANDOUT 25 Determining Whether Your Soil Amendment is a BSAAO***
  - ***HANDOUT 26 Application Requirements and Minimum Application Intervals***

- Subpart I
  - Use scenarios developed for actual on farm activities in the state/region.

- Subpart K
  - ***HANDOUT 27 FDA Fact Sheet: Dropped Covered Produce***
  - Use scenarios developed for actual on farm activities in the state/region.

- Subpart L
  - Use scenarios developed for actual on farm activities in the state/region.

- Subpart O
  - ➢ ***HANDOUT 28 Produce Safety Alliance: Records Required by the FSMA Produce Safety Rule***
  - Use scenarios developed for actual on farm activities in the state/region.

8. Differences Between Audits, On Farm Readiness Reviews (OFRRs), Inspections, and Investigations

9. Interactive Communications

All farms will meet the minimum requirements of the PSR in slightly to majorly different ways. Communication with the farm as to why a practice is done in that particular way and how is it meeting the minimum requirements of the PSR is crucial. Understanding of the PSR is key to making sure that an inspector is asking the farm to meet the PSR versus what the inspector wants.

- Open ended questions
  - ➢ ***HANDOUT 29 On Farm Talking Points***

- Active listening
  - ➢ ***HANDOUT 30 Active Listening Tips***

10. Interactive Inspectional Process

- The rules are not vague, they are flexible

- Establishing a systematic process

- Looking at the big picture
  - What is the farm's process?
    - Determining how each individual grower is meeting the standards of the PSR?
    - Deconstruction theory: working back from observation to causing event
    - Corrections/Corrective actions: Focus on preventing reoccurrence

11. Enforcement Discretion Documents from the FDA

- ➢ ***HANDOUT 31 Enforcement Discretion for Certain FSMA Provisions***

- What does it mean?

- What is the FDA requesting the States to do, and what are the grower's responsibilities?
  - Written Assurance
  - Food facilities that only hold produce (may include a pack house)

- Testing and monitoring agricultural water, latest communication from the water group

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12. **What is an Egregious Condition?** (Focus on the Subparts of the PSR)

- ***HANDOUT 32 Egregious Conditions Working Definition Agreed Upon Within NASDA/FDA Workgroup***

- Definition, origin, use in PSR

- The concept of imminent public health concern as an adverse consequence to health or death
  - Source and route of contamination
  - Produce entering commerce or the grower has the intention for the produce to enter commerce
  - As a single event
    - As a combination of several events

- When do you have enough elements and when do you need to take it to the next level?
  - What information do you have?
  - What did you observe?
  - Did you collect any exhibits?
  - What parts of the regulation are out of compliance?
  - Did the produce make it into commerce?
  - Does the grower understand the severity of an egregious condition?
  - Is this single event or a combination of activities?
  - Has this happened in the past at this location with this commodity?
  - Why sampling might not the best option
    - Not required by the rule
    - May be State specific
    - Focused on for-cause investigations

13. How the PSR May Apply Within Business Interactions with Other States (Group Discussion)

- Multiple covered activities in multiple states by one grower

- When a grower's activities trigger other regulations (PC, FSVP, Sanitary Transport)